VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

May 21, 2004
Fifth Floor
Board Room 3

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Regulation Committee of the Board of Pharmacy was called to order at 9:05 AM.

PRESIDING: Mike Ayotte, Committee Chair

MEMBERS PRESENT: Michelle Easton (Alternate)
Bobby Ison
Leo Ross
Willie Brown

MEMBERS ABSENT: John Beckner

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Ralph A. Orr, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine Yeatts, Senior Regulatory Analyst

EMERGENCY RULES ON DELEGATION – HB577: Ms. Yeatts gave an overview of HB577 and provided a generic draft regulation for the delegation of informal fact finding to agency subordinates. The committee reviewed the draft and recommended some wording changes and changes to the list of types of cases that may not be delegated. The revised draft will be presented at the June 8, 2004 board meeting.

REVIEW NOIRA COMMENTS AND MAKE RECOMMENDATION ON PROPOSED RULE ON THE 2YR TO 1YR PRN REFILL AUTHORITY: Ms. Russell presented the Notice of Intended Regulatory Action (NOIRA) comment received from the Board of Medicine recommending the Board of Pharmacy not proceed with the adoption of a proposed amendment to its regulations on refills of Schedule VI drugs. The committee discussed patient safety concerns and other reasons for making the change to the regulation. Mr. Brown moved that the committee recommend to the board to move forward with proposed rules to change the regulation.

REVIEW NEED FOR REGULATION ON OUTSOURCING OF DATA ENTRY AND DUR BY HOSPITALS AND OTHER SETTINGS:

Ms. Russell advised the committee that Joint Commission on Accreditation of Healthcare Organizations now requires prospective review by a pharmacist of medication orders in hospitals prior to administration of the medication, and that all hospital pharmacies that are not open 24 hours a day are trying to outsource this process to pharmacists in other hospitals, contract pharmacists, and sometimes pharmacists located outside Virginia. While the Board is getting ready to consider 1 pilot application and awaiting 2 more applications to allow for offsite order review and entry into the pharmacy computer system, it is has become evident that the need is too widespread to be able to be addressed by pilot programs, and needs to be addressed in regulation. The board has also approved a pilot program for retail offsite order entry that should also be addressed in regulation. Mr. Ison moved that the committee recommend to the board that a NOIRA be issued to begin the regulation process to address this issue.

DISCUSS NEED FOR NOIRA FOR WHOLESALE DISTRIBUTOR REGULATIONS:

Ms. Russell discussed the need to review the current regulations for wholesale distributors in light of recent counterfeiting activities in other states. She provided a copy of the new Model Rules for the Licensure of Wholesale Distributors from the National Association of Boards of Pharmacy (NABP). Mr. Ayotte reported he had attended a conference in Florida that reported on Florida's experience with counterfeiting and wholesale distribution. He stated that there are significant burdens associated with maintaining a paper pedigree, and that RFID technology may replace the need for paper pedigrees within just a few years. He stated that increasing the licensing requirements and the inspection process in Florida has greatly reduced the problem. Ms. Yeatts suggested these rules be placed in a separate chapter of regulation as the general pharmacy regulations are already too big to easily find anything. Mr. Ross moved to recommend to the board that a NOIRA be issued to begin the process of amending regulations on wholesale distributors, and further that a subcommittee be appointed to begin work on drafting proposed regulations.

REVIEW NEED FOR REVISION OF PHYSICIAN SELLING DRUGS REGULATIONS:

The committee discussed the need for reviewing this set of regulations, both due to possible inconsistencies with recent changes in law and other pharmacy regulations, and also to comply with requirements for periodic review of existing regulations. Mr. Brown moved to recommend to the board to issue a notice of periodic review to begin review process for this regulation.

REVIEW DRAFT SCHEDULING BILL:

Ms. Russell discussed the necessity of updating the Code to comply with changes with the federal schedules. Mr. Casway suggested it may be possible to adopt the federal schedules by reference in the code and still keep any additions or differences that are currently in place. Ms. Russell will draft language to present at the next full board meeting.

DISCUSS THE NEED TO STRENGTHEN LAWS TO PREVENT

Ms. Russell discussed the fact that currently counterfeiting a Schedule VI controlled substance is only a Class 1 or 2 misdemeanor. SB325 which was passed this session appears to have been an attempt to strengthen the penalties

COUNTERFEITING: against counterfeiting, but did not actually effect a change in penalty. Mr. Ross moved to recommend to the Board to propose legislation to strengthen SB325. Ms. Russell will draft language for the next full board meeting.

DISCUSS THE NEED FOR CHANGES TO THE NON-RESIDENT PHARMACY LAW: Ms. Russell discussed several areas of concern with the current non-resident pharmacy law. First, the board needs the authority to summarily suspend a non-resident pharmacy registration if it no longer has a resident license or permit, or if further registration in Virginia represents substantial risk of harm to the public. Second, if Congress passes a law that will allow importation of drugs from Canada, the board should be positioned to require registration of any Canadian pharmacy that ships drugs into the Commonwealth. The committee asked staff to review other state laws to see how they deal with these issues and asked Ms. Russell, Ms. Yeatts and Mr. Casway to work on draft legislation. The committee also recommended that the two issues be divided into two separate legislative proposals, so that if the Canadian issue needed to be withdrawn in the event Congress does not act or due to opposition, that the legislation enhancing the Board's authority to summarily suspend will not be affected.

DISCUSS THE NEED FOR CHANGES TO THE COMPOUNDING LAW: Ms. Russell explained that there have been a number of issues addressed with respect to the compounding law, and that there may need to be some revisions. The committee reviewed issues and provided some direction to begin drafting a legislative proposal. Ms. Russell agreed to attempt to draft some changes with assistance from Mr. Ison. If possible a draft will be presented to the full board on June 8.

NEXT MEETING: To be determined at the June 8, 2004 board meeting based on need. There may be a need for subcommittees to meet before reconvening the full committee.

ADJOURN: The meeting was adjourned at 12:15 PM.

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Elizabeth Scott Russell, Executive Director

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Mike Ayotte, Committee Chair

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Date